110TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
110–566

CYTOLOGY PROFICIENCY IMPROVEMENT ACT OF 2008

APRIL 8, 2008.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. DINGELL, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 1237]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1237) to amend the Public Health Service Act to provide revised standards for quality assurance in screening and evaluation of gynecologic cytology preparations, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

AMENDMENT

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Cytology Proficiency Improvement Act of 2008".

SEC. 2. REVISED STANDARDS FOR QUALITY ASSURANCE IN SCREENING AND EVALUATION OF GYNECOLOGIC CYTOLOGY PREPARATIONS.

(a) IN GENERAL.—Section 353(f)(4)(B)(iv) of the Public Health Service Act (42 U.S.C. 263a(f)(4)(B)(iv)) is amended to read as follows:

"(iv) requirements that each clinical laboratory—

"(I) ensure that all individuals involved in screening and interpreting cytological preparations at the laboratory participate annually in a continuing medical education program in gynecologic cytology that—

"(aa) is approved by the Accrediting Council for Continuing Medical Education or the American Academy of Continuing Medical Education; and

"(bb) provides each individual participating in the program with gynecologic cytological preparations (in the form of referenced glass slides or equivalent technologies) designed to improve the locator, recognition, and interpretive skills of the individual;

"(II) maintain a record of the cytology continuing medical education program results for each individual involved in screening and interpreting cytological preparations at the laboratory;

"(III) provide that the laboratory director shall take into account such results and other performance metrics in reviewing the performance of individuals involved in screening and interpreting cytological preparations at the laboratory and, when necessary, identify needs for remedial training or a corrective action plan to improve skills; and

"(IV) submit the continuing education program results for each individual and, if appropriate, plans for corrective action or remedial training in a timely manner to the laboratory's accrediting organization for purposes of review and on-going monitoring by the accrediting organization, including reviews of the continuing medical education program results during on-site inspections of the laboratory.".

(b) EFFECTIVE DATE AND IMPLEMENTATION; TERMINATION OF CURRENT PROGRAM OF INDIVIDUAL PROFICIENCY TESTING.—

(1) EFFECTIVE DATE AND IMPLEMENTATION.—Except as provided in paragraph (2), the amendment made by subsection (a) applies to gynecologic cytology services provided on or after the first day of the first calendar year beginning 1 year or more after the date of the enactment of this Act, and the Secretary of Health and Human Services (hereafter in this subsection referred to as the "Secretary") shall issue final regulations implementing such amendment not later than 270 days after such date of enactment.

(2) TERMINATION OF CURRENT INDIVIDUAL TESTING PROGRAM.—The Secretary of Health and Human Services shall terminate the individual proficiency testing program established pursuant to section 353(f)(4)(B)(iv) of the Public Health Service Act (42 U.S.C. 263a(f)(4)(B)(iv)), as in effect on the day before the date of the enactment of subsection (a), at the end of the calendar year which includes the date of enactment of the amendment made by subsection (a).

PURPOSE AND SUMMARY

The purpose of H.R. 1237, the "Cytology Proficiency Improvement Act of 2008", is to amend the Public Health Service Act to provide revised standards for quality assurance in screening and evaluation of gynecologic cytology preparations, and for other purposes.

BACKGROUND AND NEED FOR LEGISLATION

The American Cancer Society estimates that approximately 11,150 cases of invasive cervical cancer are diagnosed each year in the United States. Cervical cancer was once a leading cause of cancer death among American women. This trend is changing, however, in part due to the increased use of the Papanicolaou (Pap)

test—a screening procedure that can identify changes in the cervix before cancer develops and find cancer in its early and most curable stages. Currently, women who are diagnosed and treated in the early stages of developing cervical cancer have a 92 percent survival rate.

In 2005, the Federal Government launched a program to begin proficiency testing of pathologists and other laboratory professionals who perform Pap tests. The program was designed, however, using regulations written in 1992 to implement the Clinical Laboratory Improvement Amendments of 1988 (CLIA). In the 13 years between the regulation and the program's start, significant advancements in the science and practice of Pap tests have been made.

H.R. 1237 recognizes the deficiencies in the current program and would modernize the program's approach so that diagnostic skills can be adequately assessed and improved through mandated educational testing that reflects complex and state-of-the-art practice.

HEARINGS

There were no hearings held in connection to the bill reported by the Committee.

COMMITTEE CONSIDERATION

On Tuesday, March 11, 2008, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1237, amended, to the full Committee for consideration, by a voice vote. On Thursday, March 13, 2008, the full Committee met in open markup session and ordered H.R. 1237 favorably reported to the House, as amended by the Subcommittee on Health, by a voice vote. No amendments were offered during full Committee consideration.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken on amendments or in connection with ordering H.R. 1237 reported to the House. A motion by Mr. Dingell to order H.R. 1237 favorably reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Regarding clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the oversight findings of the Committee regarding H.R. 1237 are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objective of H.R. 1237 is to amend the Public Health Service Act to require the Secretary of Health and Human Services (HHS) to revise national quality assurance standards to assure consistent performance by laboratories of valid and reliable cytology services, to include requirements that each clinical laboratory: (1) ensure that all individuals involved in screening and interpreting

cytological preparations participate annually in an approved continuing medical education (CME) program in gynecologic cytology that provides each participant with gynecologic cytological preparations designed to improve locator, recognition, and interpretive skills; (2) maintain a record of the cytology CME program results for each individual involved in screening and interpreting cytological preparations at the laboratory; (3) provide that the laboratory director shall take into account such results and other performance metrics in reviewing the performance of individuals and, when necessary, identify needs for remedial training or a corrective action plan to improve skills; and (4) submit the CME program results for each individual and, if appropriate, plans for corrective action or remedial training in a timely manner to the laboratory's accrediting organization for purposes of review and on-going monitoring by the accrediting organization, including reviews of the CME program results during on-site inspections of the laboratory. Lastly, H.R. 1237 requires the Secretary of HHS to terminate individual proficiency testing that was in effect before enactment of this Act.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 1237 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARKS AND TAX AND TARIFF BENEFITS

Regarding compliance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 1237 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate on H.R. 1237 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate on H.R. 1237 provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

MARCH 31, 2008.

Hon. JOHN D. DINGELL,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1237, a bill to amend the Public Service Act to provide revised standards for quality assurance in screening and evaluation of gynecologic cytology preparations.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Lori Housman.

Sincerely,

ROBERT A. SUNSHINE
(For Peter R. Orszag, Director).

Enclosure.

H.R. 1237—A bill to amend the Public Service Act to provide revised standards for quality assurance in screening and evaluation of gynecologic cytology preparations

H.R. 1237 would amend the Clinical Laboratory Improvement Act (CLIA) by requiring clinical laboratories to ensure that all individuals involved in screening and interpreting cytological preparations participate in annual continuing medical education programs in gynecologic cytology. The bill would repeal the current requirement for proficiency testing for laboratory personnel performing cytology laboratory tests.

CLIA activities, which are administered by the Centers for Medicare & Medicaid Services (CMS), are funded though user fees, which cover 100 percent of the cost of implementing the program. This legislation would have a minor impact on CMS's workload. However, because the CLIA program recovers 100 percent of its costs through fees (which are accounted for in the budget as offsetting collections), any change in its administrative costs would be offset by an equal change in the fees that CMS charges. Hence, CBO estimates that implementing H.R. 1237 would have no net budgetary effect. Enacting the legislation would not affect direct spending or revenues.

The bill would require clinical laboratories, including laboratories of public and private hospitals, to comply with record-keeping and management standards for personnel performing cytology laboratory tests. That requirement would impose intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates, however, that the costs to laboratories would be small because compliance would probably involve minor adjustments to existing administrative procedures.

The bill also would impose a private-sector mandate on individuals who screen and interpret cytological preparations by requiring them to participate in continuing medical education programs. CBO estimates that the costs of carrying out that mandate also would be small because only several thousand individuals would be subject to the education requirements and most of them are already enrolled in such programs. Thus, CBO estimates that the costs to governmental and private-sector entities of the mandates in the bill would be small and would not exceed the thresholds established in UMRA ($68 million for intergovernmental mandates and $136 million for private-sector mandates, in 2008 adjusted annually for inflation).

The CBO staff contacts for this estimate are Lori Housman (for federal costs), Lisa Ramirez-Branum (for the state and local impact), and Patrick Bernhardt (for the private-sector impact). This estimate was approved by Keith J. Fontenot, Deputy Assistant Director for Health and Human Resources, Budget Analysis Division.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates regarding H.R. 1237 prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act would be created by H.R. 1237.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for H.R. 1237 is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian Tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that H.R. 1237 does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act of 1995.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 establishes the short title of the Act as the "Cytology Proficiency Improvement Act of 2008".

Section 2. Revised standards for quality assurance in screening and evaluation of gynecologic cytology preparations

Section 2 of this legislation amends Section 353f(4)(B)(iv) of the Public Health Service Act (42 U.S.C. 263a(f)(4)(B)(iv)).

Section 2 requires the Secretary of Health and Human Services to revise national quality assurance standards to assure consistent performance by laboratories of valid and reliable cytology services. This includes regulations requiring that each clinical laboratory ensure all individuals involved in screening and interpreting cytological preparations participate annually in an approved CME program in gynecologic cytology that provides each participant with gynecologic cytological preparations (in the form of referenced glass slides or equivalent technologies) designed to improve locator, recognition, and interpretive skills. These CME programs must be approved by the Accrediting Council for Continuing Medical Education or the American Academy of Continuing Medical Education.

Section 2 requires that each clinical laboratory maintain a record of the cytology CME program results for each individual involved in screening and interpreting cytological preparations at the laboratory. Furthermore, H.R. 1237 requires that the laboratory director shall take into account such results and other performance metrics in reviewing the performance of individuals involved in screening and interpreting cytological preparations at the labora-

tory and, when necessary, identify needs for remedial training or a corrective action plan to improve skills.

Section 2 requires that each clinical laboratory director submit the CME program results for each individual and, if appropriate, plans for corrective action or remedial training in a timely to the laboratory's accrediting organization for purposes of review and ongoing monitoring by the accrediting organization, including reviews of the CME program results during on-site inspections of the laboratory.

Section 2 states that these new regulations shall be implemented on or after the first day of the first calendar year beginning 1 year or more after the date of enactment of this Act, and the Secretary of HHS shall issue final regulations not later than 270 days after such date of enactment.

Section 2 states that the Secretary of HHS shall terminate the existing individual proficiency testing program at the end of the calendar year in which the Act was enacted.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART F—LICENSING—BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

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Subpart 2—Clinical Laboratories

CERTIFICATION OF LABORATORIES

SEC. 353. (a) * * *

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(f) STANDARDS.—

(1) * * *

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(4) NATIONAL STANDARDS FOR QUALITY ASSURANCE IN CYTOLOGY SERVICES.—

(A) * * *

(B) STANDARDS.—The standards established under subparagraph (A) shall include—

(i) * * *

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[(iv) periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions,]

(iv) requirements that each clinical laboratory—

(I) ensure that all individuals involved in screening and interpreting cytological preparations at the laboratory participate annually in a continuing medical education program in gynecologic cytology that—

(aa) is approved by the Accrediting Council for Continuing Medical Education or the American Academy of Continuing Medical Education; and

(bb) provides each individual participating in the program with gynecologic cytological preparations (in the form of referenced glass slides or equivalent technologies) designed to improve the locator, recognition, and interpretive skills of the individual;

(II) maintain a record of the cytology continuing medical education program results for each individual involved in screening and interpreting cytological preparations at the laboratory;

(III) provide that the laboratory director shall take into account such results and other performance metrics in reviewing the performance of individuals involved in screening and interpreting cytological preparations at the laboratory and, when necessary, identify needs for remedial training or a corrective action plan to improve skills; and

(IV) submit the continuing education program results for each individual and, if appropriate, plans for corrective action or remedial training in a timely manner to the laboratory's accrediting organization for purposes of review and on-going monitoring by the accrediting organization, including reviews of the continuing medical education program results during on-site inspections of the laboratory.

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